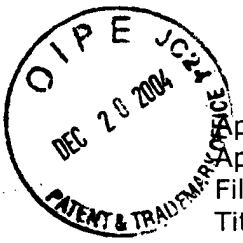
AF 3738

BSI-010US4 PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No:	09/977,826
Applicant:	George Goicoechea et al.
Filed:	October 15, 2001
Title:	BIFURCATED ENDOLUMINAL PROSTHESIS
TC/A.U.:	3738
Examiner:	William H. Matthews
Confirmation No.:	4645
Notice of Appeal Filed:	July 14, 2004
Docket No.:	BSI-010US4

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Commissioner for Patents
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Alexandria, VA 22313-1450

S I R :

Appellants hereby request consideration and reversal of the Final Rejection dated January 26, 2004, and the Advisory Action dated June 2, 2004, of claims 20, 22-25, 31-33, 39, 41, 43-49 and 54-57.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.37(a)(2) and 41.20(b)(2), together with any extension fee required in connection with the filing of this Brief, are provided herewith.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Scimed Life Systems, Inc., One SciMed Place, Maple Grove, MN 55311-1566.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to the subject matter of this Appeal, except as follows:

Interference No. 104,083. A copy of the decision of the Board of Patent Appeals and Interferences in this Interference is provided in the Related Proceedings Appendix (Section X) at Tab 1. This Interference involved related Application Serial No. 08/461,402 of Andrew H. Cragg et al., filed June 5, 1995, titled BIFURCATED ENDOLUMINAL PROSTHESIS.

Interference No. 104,192. A copy of the decision of the Board of Patent Appeals and Interferences in this Interference is provided in the Related Proceedings Appendix (Section X) at Tab 2. This Interference also involved related Application Serial No. 08/461,402.

Boston Scientific Technology, Inc. v. Medtronic Aneurx, Inc., et al., U.S. District Court for the District of Columbia, Civil Action No. 01 CV 2015. This is an appeal from the decision in Interference No. 104,192. The following interlocutory orders and/or decisions have been entered in this appeal, with copies included in the Related Proceedings Appendix (Section X) at the indicated Tabs:

DATE	ORDER OR OPINION	TABS
11/15/01	Order	3
12/21/01	Order	4
5/2/02	Order	5
8/30/03	Memorandum Opinion and Order	6
3/25/04	Stipulation and Order	7
9/12/04	Protective Order	8
12/14/04	Joint Stipulated Request to Extend Discovery	9

There has not been a final decision in this appeal as of the date of the filing of this Brief.

III. STATUS OF CLAIMS

Claims 20, 22-41, 43-49 and 54-62 are pending. A copy of the pending claims involved in this appeal is provided in the Claims Appendix (Section VIII).

Claims 20, 22-25, 31-33, 39, 41 and 43-49 stand rejected (paragraph 7 of the Advisory Action dated June 2, 2004 did not list the status of claims 54-57, which had been rejected in the Final Rejection dated January 26, 2004). Claims 27-30 were objected to. Claims 1-19, 21, 42, and 50-53 have been canceled. Claims 26, 34-38, 40 and 58-62 were withdrawn from consideration.

To assist the Board in correlating dependent claims with their corresponding independent claims, appellants provide the following chart of the pending claims that have not been withdrawn:

20	Dependent on claim 54
22	Dependent on claim 20
23	Dependent on claim 20
24	Dependent on claim 20
25	Dependent on claim 20
27	Dependent on claim 20
28	Dependent on claim 27
29	Dependent on claim 28
30	Dependent on claim 29
31	Dependent on claim 54
32	Dependent on claim 54
33	Dependent on claim 32
39	Dependent on claim 54
41	Dependent on claim 31
43	Dependent on claim 54
44	Dependent on claim 43
45	Dependent on claim 44
46	Dependent on claim 44
47	Dependent on claim 43
48	Dependent on claim 47
49	Dependent on claim 47
54	Independent
55	Dependent on claim 20
56	Independent
57	Dependent on claim 56

IV. STATUS OF AMENDMENTS

No amendment to the claims was filed subsequent to Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 54

The invention recited in claim 54 is a stent including a plurality of hoops aligned along a common axis. Each of the hoops is oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent. Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices that point in a direction along the longitudinal axis of the stent. The stent also includes means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

For example, and for purposes of illustration only, one exemplary embodiment of the invention is shown as stent 10 in Fig. 1A (page 19, lines 5-7; page 22, lines 17-18). Part of a stent such as stent 10 is also shown in Figs. 2A (page 19, lines 11-13; page 23, lines 11-12), 3 (page 19, lines 17-19; page 25, line 27-page 26, line 1), and 4A (page 19, lines 20-22; page 22, lines 17-18). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). Each hoop is oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent (page 9, lines 15-19).

Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices such as apices 22 (Fig. 2A, page 23, lines 11-20) that point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

The stent also has **means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop**. This feature is recited in terms of means plus function under 35 U.S.C. § 112, sixth paragraph. Pursuant to 37 C.F.R. § 41.37(c)(1)(v), the following paragraphs set forth the structure described in the specification as corresponding to the claimed function.

The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together. The loop element may also comprise a loop formed of a thermoplastics material such, for example, as polypropylene. Alternatively, the securing means may be a bead formed of a thermoplastic material around juxtaposed apices. Also alternatively, the securing means may be a loop, ring, or staple formed of wire such as nitinol (page 10, lines 20-28). FIGS. 4B-4F are partial exploded views of embodiments of a stent illustrating exemplary means for securing juxtaposed apices of the stent (page 20, lines 1-4).

Referring to Fig. 4A, for example, juxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 which may be, for example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has a juxtaposed apex of a neighboring hoop 20 is tied to the juxtaposed apex 22 in this embodiment. In other embodiments of the invention, only some of the juxtaposed apices 22 may be secured in this way (page 25, lines 4-11).

In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in FIG. 4B. The securing means may also comprise a bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in FIG. 4C. Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in FIGS. 4D, 4E, and 4F respectively (page 25, lines 12-21).

The foregoing, exemplary structures correspond to the function recited in claim 54 of securing an apex of one hoop to a juxtaposed apex of a neighboring hoop. Equivalent structures for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop are also within the literal scope of claim 54 under 35 U.S.C. § 112, sixth paragraph.

B. Claim 23

This claim depends from claims 54 and 20 and is argued separately from claim 54. As recited in claim 20, an exemplary stent has at least one stent segment in combination with one or more additional stent segments. As recited in claim 23, the

one or more additional segments are secured to one another by connecting means that connect at least some of the apices of hoops at mating ends of the stent and the additional segments.

For example, and for purposes of illustration only, and according to one exemplary embodiment of the invention, an exemplary stent may comprise at least one stent segment such as stent segment 12 in combination with one or more additional stent segments such as stent segments 14, 18, 16, 42, and 44 (Figs. 1A, 1B).

Additional stent segments such as stent segment 12 may be secured to another stent segment such as stent segment 14 by **connecting means connecting at least some of the apices of hoops at mating ends of the stent and the additional segments**. This feature is recited in terms of means plus function under 35 U.S.C. § 112, sixth paragraph. Pursuant to 37 C.F.R. § 41.37(c)(1)(v), the following paragraphs set forth the structure described in the specification as corresponding to the claimed function.

Juxtaposed apices 22 of each of the examplary frustoconical parts 14, 18 shown in Figs. 1 and 3 can be tied together using 0.003" polyproplyene filaments. The first and second frustoconical parts 14, 18 are secured to the distal end 26 of the exemplary proximal part 12 of the exemplary stent 10 in transversely spaced relation as shown in FIG. 1A by securing the apices 22 of the hoop 20 forming the wider proximal end 30 of each of the frustoconical parts 14, 18 to juxtaposed apices 22 of the hoop 20 on the distal end 26 of the proximal part 12 (page 26, lines 8-18). As shown in Fig. 4A, the proximal end 34 of the distal part 16 is secured to the narrower distal end 32 of the first frustoconical part 14 by tying each apex 22 on the proximal end 34 of the first distal part 16 to a juxtaposed apex on the distal end 32 of the first frustoconical part 14 using, in an exemplary embodiment, 0.003" polypropylene filaments (page 26, line 25-page 27, line 2). The distal end of the exemplary frustoconical proximal part 42 shown in Fig. 1B is secured to the proximal end of the distal part 44 by securing juxtaposed apices using polypropylene filaments as described above (page 29, lines 18-21).

The connecting means may also be circumferentially spaced barbs or hooks 43, as shown in Fig. 1B, which engage in the wire skeleton of the second frustoconical part 18 of the exemplary bifurcated stent 10 (page 30, lines 8-12). Fig. 1B shows that the barbs or hooks 43 connect some of the apices of hoops at mating ends of the exemplary stent 10 such as segments 18 and 42.

The foregoing, exemplary structures correspond to the function recited in claim 23. Equivalent structures for connecting at least some of the apices of hoops at mating ends of the stent and the additional segment are also within the literal scope of claim 23 under 35 U.S.C. § 112, sixth paragraph.

C. Claim 55

This claim depends from claims 54 and 20 and is argued separately from claim 54. As recited in claim 20, an exemplary stent has at least one stent segment in combination with one or more additional stent segments. As recited in claim 55, at least one of the additional stent segments has a plurality of hoops aligned along a common axis. Each of the hoops in the additional stent segment is oriented in a plane that is substantially perpendicular to the longitudinal axis of the additional stent segment. Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices that point in a direction along the longitudinal axis of the additional stent segment.

For example, and for purposes of illustration only, and according to one exemplary embodiment of the invention, an exemplary stent may comprise at least one stent segment such as stent segment 12 in combination with one or more additional stent segments such as stent segments 14, 18, 16, 42, and 44 (Figs. 1A, 1B). The exemplary first and second frustoconical parts 14, 18 of the skeleton shown in the figures are formed in substantially the same way as the proximal part 12. As shown in Fig. 3, the exemplary first and second frustoconical parts 14, 18 are each constituted by three hoops 20 of unit width (page 25, line 22-page 26, line 1). The exemplary frustoconical proximal part 42 is constructed in the same way as the frustoconical parts 14, 18 of the exemplary stent 10. The exemplary distal part 44 is constructed in the same way as the distal part 16 of the bifurcated stent 10 (page 29, lines 14-18).

Claim 55 further recites **means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop**. This feature is recited in terms of means plus function under 35 U.S.C. § 112, sixth paragraph. The structure described in the specification as corresponding to the claimed function has been set forth previously in this brief in connection with claim 54.

D. Claim 56

The invention recited in claim 56 is a stent including a tubular member that has a plurality of hoops aligned adjacent one another along the longitudinal axis of the tubular member. Each of the hoops has a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices that axially point in a direction along the longitudinal axis of the stent. At least some of the vertices axially abut and are individually connected to oppositely pointed veritices of elongate elements of an adjacent hoop. The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member.

For example, and for purposes of illustration only, and according to one exemplary embodiment of the invention, a stent such as stent 10 includes a tubular member (page 8, lines 8-10). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). The exemplary hoops are aligned adjacent one another along the longitudinal axis of the tubular member (Fig. 1A; page 9, lines 19-27; page 23, lines 24-27).

Each of the hoops includes a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices such as vertices 22 (Fig. 2A, page 23, lines 11-20) that axially point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

At least some of the vertices axially abut (Figs. 2A, 4A) and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop (Figs. 2A, 4A). For example, a loop element of a suture material connects oppositely pointed vertices of adjacent hoops (page 10, lines 18-23). Exemplary suture material

is shown as element 99a in Fig. 4B (page 25, lines 13-15). Other materials for connecting oppositely pointed vertices of adjacent hoops are shown in Figs 4A and 4C to 4F (page 25, lines 4-21).

The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member (page 9, lines 15-19; page 10, lines 2-5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are set forth in the Final Rejection dated January 26, 2004. The Advisory Action dated June 2, 2004 did not list the status of claims 54-57.

Claims 20, 22-24, 31-33, 41, 54, and 55 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,405,377 issued to Cragg.

Claims 20, 22-24, 31, 54-57 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,370,683 issued to Fontaine.

Claims 20, 22-25, 39, 43, 44, 47, and 54-55 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,104,404 issued to Wolff.

Claims 45, 46, 48, and 49 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,104,404 issued to Wolff as applied to claims 54, 43, 44, and 47 and further in view of U.S. Patent 5,824,039 issued to Piplani et al.

VII. ARGUMENT

A. Rejection under 35 U.S.C. § 102(e) over U.S. Patent No. 5,405,377 issued to Cragg

1. Claims 54, 31-33, 41

Independent claim 54 recites that "each of said hoops [are] oriented in a plane substantially perpendicular to the longitudinal axis of the stent." The substantially perpendicular hoop configuration of claim 54 is distinguishable from Cragg's helical configuration, and the distinction between these configurations was

identified in Applicants' specification at page 9, lines 13-19. Specifically, at page 9, lines 13-19 of Applicants' specification, reference is made to the helical configuration disclosed in EP-A-0556850,[1] which is the European patent that corresponds to the cited U.S. Cragg reference. Applicants' specification states that, in addition and as an alternative to Cragg's helical configuration, "the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent."

Page 4, paragraph 4 of the Final Office Action cites Figures 1-4 and column 2, line 40, through column 3, line 4, of Cragg in support of this rejection. The cited portions of Cragg fail, however, to disclose hoops oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

As a preliminary matter, Cragg specifically states that "the drawings are not necessarily to scale" (column 2, lines 31-34), and it is therefore improper to support this rejection based on drawing measurements. Section 2125 of the MPEP states that it is not proper to use drawings to make arguments based on measurements when the drawings are not to scale:

> When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ 2d 1487, 1491 (Fed. Cir. 2000)

In Hockerson, the Court stated:

> The '792 patent is devoid of any indication that the proportions of the groove and fins are drawn to scale. . .Under our precedent, . . .it is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue. *See In re Wright*, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA 1977) ("Absent any

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[1] Although a copy of the European patent was provided to the Office during prosecution, a copy has not been provided in an Evidence Appendix to this Brief because Rule 41.37(c)(ix) only permits copies of evidence submitted pursuant to §§1.130, 1.131, or 1.132 or any other evidence entered by the examiner to be included in an Evidence Appendix. Nevertheless, the European patent is part of the record on appeal because it is referenced in Applicants' specification at page 3, line 12.

written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.") 222 F.3d at 956, 55 USPQ 2d at 1491.

MPEP 2125 also discusses *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977) regarding the use of drawings. The MPEP points out that the Solicitor had made an argument based on the Solicitor's comparison of the relative dimensions of the drawing figures in the appellant's application with the dimension in the drawing figures in the Bauer prior art device. The Solicitor had argued that the comparison revealed that Bauer use a chime length of roughly ½ to 1 inch for a whiskey barrel. The Court disagreed with the Solicitor's comparison because the Solicitor "ignore[d] the fact that Bauer does not disclose that his drawings are drawn to scale." 569 F.2d at 1127, 193 USPQ at 335. However, the MPEP points out, the Court agreed with the Solicitor's argument that the Bauer reference generally taught that "whiskey losses are influenced by the distance the liquor needs to traverse the pores of the wood." 569 F.2d at 1127, 193 USPQ at 335.

In both of the cases cited in the MPEP, the prior art references did not disclose that its drawings were drawn to scale. Consequently, the Court refused to accord any weight to arguments based on dimensions purportedly discerned from the drawings.

Because the Cragg reference expressly states that the drawings are not necessarily drawn to scale, there is no basis for the Office to contend that the hoops in Cragg are substantially perpendicular. Consequently, there is no basis for the Office to conclude that "the hoops [in Cragg] are substantially perpendicular, i.e. greater than 50% perpendicular to the longitudinal axis."

Additionally, page 2, paragraph 2 of the Final Office Action cites to a dictionary definition of "substantial" ("being largely but not wholly that which is specified"), but reaches an erroneous conclusion that the term "substantially perpendicular to the longitudinal axis" means "greater than 50% perpendicular to the longitudinal axis." Because items that are exactly perpendicular to each other are at a 90° angle relative to each other, 50% of exactly perpendicular (a 90° angle) is therefore 45°. Under the Final Office Action's analysis, a prior art reference need only show an angle of 45.1° in order to anticipate the "substantially perpendicular"

limitation of claim 54. There is absolutely no reasonable basis, however, for the Final Office Action to have concluded that an angle of 45.1° defines an angle that is "substantially perpendicular."

Furthermore, the dictionary definition of "substantial" fails to support the Final Office Action's interpretation of this claim. There is no basis in the record for the Final Office Action to adopt a rule of 50% of perpendicular as a standard for "substantially perpendicular" and to conclude that a 45.1° angle defines a relationship between two items that are "largely but not wholly" perpendicular. It is respectfully submitted that a 45.1° angle is not sufficiently close to a 90° angle to be considered "largely" a 90° angle, and such an interpolation of the dictionary definition of "substantial" is not justified.

As alluded to previously, it is significant that Applicants' specification expressly distinguished their device from the Cragg device. Applicants' expressly distinguished their invention from the Cragg device by stating that, as an alternative to Cragg's helical configuration, "the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent." By identifying their substantially perpendicular hoop configuration as an alternative to the helical configuration of Cragg, Applicants' use of the term "substantially perpendicular" specifically excludes Cragg's helical configuration.

Moreover, *In re Gartside*, 203 F.3d 1305, 53 USPQ 2d 1769 (Fed. Cir. 2000) requires the Board to determine

> whether the agency action, findings, and conclusions were supported by substantial evidence, or, in other words, whether a reasonable factfinder could have arrived at the agency's decision. The Supreme Court has described "substantial evidence" as "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." MPEP 1216.01.

The Final Office Action has not produced substantial evidence demonstrating that applicants' device, with its "substantially perpendicular" configuration, is disclosed by Cragg as required by *In re Gartside*.

For the foregoing reasons, Cragg fails to anticipate claim 54 and claims 31-33 and 41, which are directly or indirectly dependent on claim 54. Accordingly, the Final Rejection of claims 54, 31-33 and 41 under 35 U.S.C. § 102(e) over U.S. Patent No. 5,405,377 issued to Cragg must be reversed.

2. Claim 20

Claim 20 depends from claim 54. Claim 20 recites that the stent of claim 54 comprises "at least one stent segment in combination with one or more additional stent segments." Paragraph 4 of the Final Office Action does not explain how Cragg anticipates claim 20. Although Cragg has "a plurality of connected spirals or hoops" (column 1, lines 57-58), it is made from "a predetermined length of wire . . . defining a continuous helix" (column 1, lines 55-57). Cragg does not disclose or suggest "at least one stent segment in combination with one or more additional stent segments." Accordingly, the Final Rejection of claim 20 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,405,377 issued to Cragg must be reversed.

3. Claim 22

Claim 22 depends from claims 54 and 20. As noted above, claim 20 recites that the stent of claim 54 comprises "at least one stent segment in combination with one or more additional stent segments." Claim 22 adds that the "one or more additional segments are axially aligned with one another." Apparently referring to claim 22, page 4, paragraph 4 of the Final Office Action states that all of the hoops in Cragg "are axially aligned." Because Cragg has does not disclose or suggest "one or more additional segments" as explained above in connection with claim 20, Cragg also does not disclose "one or more additional segments . . . axially aligned with one another" as recited in claim 22.

For the foregoing reasons, Cragg fails to anticipate claim 22. Accordingly, the Final Rejection of claim 22 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,405,377 issued to Cragg must be reversed.

4. Claim 23

Claim 23 depends from claims 54 and 20. Claim 23 recites that the "one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments." Though Cragg shows loop members 12 connecting adjacent apices of adjacent helix hoops (column 2, lines 45-47), Cragg does not show or

suggest connecting one or more additional segments to one another by connecting means that connect "apices of hoops at mating ends of said stent and said additional segments." Specifically, Cragg does not disclose or suggest "one or more additional segments" and therefore cannot disclose or suggest an additional segment so secured.

For the foregoing reasons, Cragg fails to anticipate claim 23. Accordingly, the Final Rejection of claim 23 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,405,377 issued to Cragg must be reversed.

5. Claim 24

Claim 24 depends from claims 54 and 20. Claim 24 recites that "adjacent hoops are of the same diameter." Apparently referring to claim 24, page 4, paragraph 4 of the Final Office Action states that all of the hoops in Cragg are of equal diameter. Because Cragg does not disclose one or more additional stent segments, Cragg fails to anticipate claim 24.

Accordingly, the Final Rejection of claim 24 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,405,377 issued to Cragg must be reversed.

6. Claim 55

Claim 55 depends from claims 54 and 20. Claim 55 contains recitations about at least one of the "additional stent segments." It recites that the additional stent segment has a plurality of hoops aligned along a common axis and that each of the hoops are "oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment."

As pointed out above, Cragg does not disclose additional stent segments. As a result, Cragg does not disclose a structure that such additional stent segments can take. Accordingly, Cragg does not disclose a stent segment having hoops that are "oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment."

For the foregoing reasons, Cragg fails to anticipate claim 55. Accordingly, the Final Rejection of claim 55 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,405,377 issued to Cragg must be reversed.

B. Rejection under 35 U.S.C. § 102(e) over U.S. Patent No. 5,370,683 issued to Fontaine

1. Claims 54 and 31

Claim 54 recites that "each of said hoops [are] oriented in a plane substantially perpendicular to the longitudinal axis of the stent" as mentioned previously.

The Final Office Action relies upon Figures 6, 9, 10, and 14 as well as lines 42-56 of column 4 of Fontaine. Fontaine fails, however, to disclose that *each* of the hoops is oriented in a plane substantially perpendicular to the longitudinal axis of the stent as recited in claim 54. In fact, the disclosure in Fontaine cited in the Final Office Action is strictly limited to wave forms "a", "b" and "c" in Figure 6 of Fontaine. Instead of the structure recited in claim 54, Fontaine teaches (at column 4, lines 13-15, for example) an expanded wave form wrapped, *in a spiral*, around a mandril.

Page 2, paragraph 3 of the Final Office Action again relies on an erroneous conclusion that the term "substantially perpendicular to the longitudinal axis" means "greater than 50% perpendicular to the longitudinal axis." Applicants incorporate by reference the MPEP citations and case law citations set forth above in connection with the Cragg reference.

Page 2, paragraph 3 of the Final Office Action, also relies upon Figures 13-16 of Fontaine, stating that those figures "clearly show embodiments in which the vertices align in a common plane perpendicular to the longitudinal axis of the stent." It is respectfully submitted that the Final Office Action is wrong in this regard. Such an interpretation of those figures contradicts the disclosure of Fontaine, which is limited to a spirally wound configuration. See, for example, the general description of the preferred embodiment at column 7, lines 55-59, which refers to the hoops in the preferred embodiment as having a spiral shape. It also ignores the recitation in claim 54 that "*each* of said hoops [are] oriented in a plane substantially perpendicular to the longitudinal axis of the stent."

For the foregoing reasons, the Fontaine reference fails to anticipate claims 54 and 31. Accordingly, the Final Rejection of claims 54 and 31 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,370,683 issued to Fontaine must be reversed.

2. Claim 20

Claim 20 depends from claim 54. Claim 20 recites that the stent recited in claim 54 comprises "at least one stent segment in combination with one or more additional stent segments." Paragraph 5 on page 4 of the Final Office Action does not explain how Fontaine anticipates claim 20. The device in Fontaine is "formed from a single filament of low memory biocompatible material having a series of U-shaped bends" (column 2, lines 31-33). Although Fig. 10 shows a number of cells having U-shaped bends, Fig. 10 does not disclose or suggest "at least one stent segment in combination with one or more additional stent segments" as recited in claim 20.

For the foregoing reasons, the Fontaine reference fails to anticipate claim 20. Accordingly, the Final Rejection of claim 20 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,370,683 issued to Fontaine must be reversed.

3. Claim 22

Claim 22 depends from claims 54 and 20. As noted above, claim 20 recites that the stent recited in claim 54 comprises "at least one stent segment in combination with one or more additional stent segments." Claim 22 adds that the "one or more additional segments are axially aligned with one another."

Apparently referring to claim 22, paragraph 5 on page 2 of the Final Office Action states that all of the hoops in Fontaine "are axially aligned." As shown above, Fontaine has "a plurality of connected spirals or hoops" (column 1, lines 57-58). It does not disclose "one or more additional segments" as recited in claims 20 and 22. Since Fontaine does not have "one or more additional segments," it also does not disclose "one or more additional segments . . . axially aligned with one another" as recited in claim 22.

For the foregoing reasons, Fontaine fails to anticipate claim 22. Accordingly, the Final Rejection of claim 22 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,370,683 issued to Fontaine must be reversed.

4. Claims 23

Claim 23 depends from claims 54 and 20. Claim 23 recites that the "one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments." Fontaine does not show connecting one or more additional

segments to one another by connecting means that connect "apices of hoops at mating ends of said stent and said additional segments." (emphasis added)

For the foregoing reasons, Fontaine fails to anticipate claim 23. Accordingly, the Final Rejection of claim 23 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,370,683 issued to Fontaine must be reversed.

5. Claim 24

Claim 24 depends from claims 54 and 20. Claim 24 recites that "adjacent hoops are of the same diameter." Apparently, referring to claim 24, paragraph 5 on page 4 of the Final Office Action asserts that all of the hoops in Fontaine are of equal diameter. Fontaine discusses only the overall diameter of a stent. See, e.g., column 6, line 41 ("[t]his arrangement increases the diameter to which the stent can be expanded") and lines 60-61 (referring to the expanded and the unexpanded diameter of the stent). Fontaine does not discuss the diameters of individual, adjacent hoops of a stent having a stent segment and one or more additional stent segments. Additionally, because the drawings in Fontaine are not necessarily drawn to scale, the Final Office Action has not produced substantial evidence demonstrating that all of Fontaine's hoops in the stent and an additional stent segment are of the same diameter as required by *In re Gartside.*

For the foregoing reasons, Fontaine fails to anticipate claim 24. Accordingly, the Final Rejection of claim 24 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,370,683 issued to Fontaine must be reversed.

6. Claim 55

Claim 55 depends from claims 54 and 20. Claim 55 contains recitations about at least one of the "additional stent segments." It recites that the additional stent segment has a plurality of hoops aligned along a common axis and that each of the hoops are "oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment." Claim 55 also recites that apices of the hoops "point along the longitudinal axis of the additional stent segment."

As pointed out above, Fontaine does not disclose additional stent segments. As a result, Fontaine does not disclose or suggest a structure that such additional stent segments take. Additionally, Fontaine fails to disclose a stent

structure in which each hoop is oriented in a plane substantially perpendicular to the stent axis.

For the foregoing reasons, Fontaine fails to anticipate claim 55. Accordingly, the Final Rejection of claim 55 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,370,683 issued to Fontaine must be reversed.

7. Claims 56 and 57

Claim 56 recites that "the vertices of *each* hoop . . . lie in a common plane *perpendicular* to the axis of the tubular member." Apparently referring to Claim 56, paragraph 5 on page 4 of the Final Office Action contends that column 4, lines 42-56 of Fontaine describe the vertices as lying in a common plane perpendicular to the longitudinal axis of the stent. It is respectfully submitted that the Final Office Action is wrong in this regard.

First, the cited lines describe the position of the peaks of only some of the peaks of a portion of the waveform. Claim 56 recites a description of "the vertices of each hoop." (emphasis added)

It is further noted that claim 56 recites "perpendicular" as opposed to "substantially perpendicular." Therefore, the strained definition of "substantially" referred to in the Final Office Action does not apply to claim 56. This strained definition was discussed above in connection with the rejection of claims 54, 31-33 and 41 based on the Cragg reference and is incorporated here by reference.

In paragraph 3 on page 2, the Final Office Action also relies upon Figs. 13-16 of Fontaine, stating that those figures "clearly show embodiments in which the vertices align in a common plane perpendicular to the longitudinal axis of the stent." However, a close examination of those figures, together with the explicit teachings of the Fontaine reference, demonstrates why it is improper for the Final Office Action to reach such a conclusion.

Specifically, Figure 8 of Fontaine shows relative positions of the U shape bends that are formed in the wire of Figure 7. Such bends, if analogous to Applicants' claimed vertices, are clearly not oriented in a plane "perpendicular" as recited in claim 56. Instead, those U shaped bends of Fontaine progress along the length of the stent. Referring to Figures 8 and 9, the bends 1-7 and 1'-7' are brought together to form the Fontaine helix, which extends along the length of the stent. The bends (or

vertices) 1-7 clearly do not align in a common plane perpendicular to the longitudinal axis of the stent. They instead progress helically along the length of the stent.

For the foregoing reasons, Fontaine fails to anticipate claim 56. Accordingly, the Final Rejection of claim 56 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,370,683 issued to Fontaine must be reversed.

C. Rejection under 35 U.S.C. § 102(b) over U.S. Patent No. 5,104,404 issued to Wolff

1. Claim 54 and 39

Claim 54 and dependent claim 39 recite "means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop." As described above, and for illustration purposes, the securing means can be used for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors; for example, the securing means may comprise a loop element of a suture material to tie the juxtaposed apices together. Also as described above, and for illustration purposes, the securing means may optionally comprise a loop element of a suture material to tie the juxtaposed apices together. See page 10, lines 16-23 of this application, for example. The securing means secures an apex of one hoop "to" a juxtaposed apex of a neighboring hoop.

Wolff relates particularly to arteries which have a curved portion, curved and recurved portions, changes in diameter, which are difficult to obtain using existing stents. See column 1, lines 14-19 of Wolff. Accordingly, Wolff discloses stent segments flexibly connected by a hinge. See Wolff at column 1, lines 45-47. This approach, according to Wolff, permits articulation between adjacent stent segments and also maintains the spacing between adjacent segments as established by the hinge lengths. According to Wolff, this maintains a space between adjacent segments as established by the hinge lengths. See Wolff at column 1, lines 47-52, for example. This spacing is illustrated by Wolff in Figs. 1, 3, 4 and 6.

The Final Office Action fails to identify any disclosure in Wolff of a means for securing an apex of one hoop to a *juxtaposed* apex of a neighboring hoop. "Juxtaposed" means "side by side." Merriam-Webster's Collegiate Dictionary, Eleventh Edition (2003). Instead, Wolff teaches away from a juxtaposed

configuration by touting the benefit of hoops spaced apart by hinge lengths. Specifically, Wolff states:

> This device utilizes a number of stent segments flexibly connected together by a hinge between each adjacent stent segment. This approach. . .maintains the spacing between adjacent segments as established by the hinge lengths." (column 1, lines 45-52) (emphasis added)

See also, column 3, lines 55-56 ("hinges 14 act as a bridge between adjacent stent segments 12"). Accordingly, while claim 54 recites that the securing means secures an apex of one hoop to a juxtaposed apex of a neighboring hoop, Wolff uses hinges to maintain spacing between adjacent hoops.

For the foregoing reasons, Wolff fails to anticipate claim 54 and dependent claim 39. Accordingly, the Final Rejection of claims 54 and 39 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,104,404 issued to Wolff must be reversed.

2. Claim 20

Claim 20 depends from claim 54. Claim 20 recites that the stent recited in claim 54 comprises "at least one stent segment in combination with one or more additional stent segments." Wolff fails to disclose a stent having the structure recited in claim 54 and further fails to suggest such a stent in combination with one or more additional stent segments.

For the foregoing reasons, the Wolff reference fails to anticipate claim 20. Accordingly, the Final Rejection of claim 20 under 35 U.S.C. § 102(b) as anticipated by Wolff must be reversed.

3. Claim 22

Claim 22 depends from claims 54 and 20. Claim 22 adds that the "one or more additional segments are axially aligned with one another." Wolff fails to suggest a stent having the structure recited in claim 54 and further fails to suggest such a stent in axial alignment with one or more additional stent segments.

For the foregoing reasons, Wolff fails to anticipate claim 22. Accordingly, the Final Rejection of claim 22 under 35 U.S.C. § 102(b) as anticipated by Wolff must be reversed.

4. Claim 23

Claim 23 depends from claims 54 and 20. Claim 20 recites that the stent recited in claim 54 comprises "at least one stent segment in combination with one or more additional stent segments." Claim 23 adds that the "one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments." Wolff does not show a stent having the structure recited in claim 54 or one or more additional segments secured by connecting means connecting at least some of the apices of hoops at mating ends of such a stent and the additional segments.

For the foregoing reasons, Wolff fails to anticipate claim 23. Accordingly, the Final Rejection of claim 23 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,104,404 issued to Wolff must be reversed.

5. Claim 24

Claim 24 depends from claims 54 and 20. Claim 24 recites that adjacent hoops of the stent recited in claim 54 are of the same diameter. Wolff does not show a stent having the structure recited in claim 54 and therefore fails to disclose such a stent with hoops of the same diameter.

For the foregoing reasons, Wolff fails to anticipate claim 24. Accordingly, the Final Rejection of claim 24 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,104,404 issued to Wolff must be reversed.

6. Claim 25

Claim 25 depends from claims 54 and 20. Claim 25 recites that adjacent hoops of the stent recited in claim 54 are of a different diameter. Wolff does not show a stent having the structure recited in claim 54 and therefore fails to disclose such a stent with hoops of differing diameters.

For the foregoing reasons, Wolff fails to anticipate claim 25. Accordingly, the Final Rejection of claim 25 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,104,404 issued to Wolff must be reversed.

7. Claims 43, 44, and 47

Claims 43, 44 and 47 depend from claim 54. Claim 43 recites a "radiopaque marker disposed on at least one end of the stent." Claim 43 recites an additional feature which is not disclosed by Wolff, namely, that a radiopaque marker

is disposed on at least one end of the stent. Apparently referring to claim 43, page 5, paragraph 6 of the Final Office Action states that "each end portion of the stent, left 12 or right 12, may have a tubular coating of radiopaque material over element 14 (see lines 63-65 of column 3)."

However, column 3, lines 63-65 does not anticipate claim 43. Referring to Figure 1, it states:

> These hinges [hinges 14], as discussed earlier, can either be made of radiopaque material or can be coated with radiopaque material to permit determining the orientation of the articulated stent. . . .

Radiopaque material on hinges 14 does not disclose the invention recited in claim 43. Claim 43 requires a radiopaque element to be "disposed on at least one end of the stent." (emphasis added) Hinges 14 of Wolff are not an "end of the stent." Instead, hinges 14 provide interconnections at intermediate intervals along the length of the stent (column 3, lines 40-41). In order to anticipate claim 43, Wolff would have to disclose a radiopaque marker on one of the ends of one of the segments 12 in Figure 1. There is no such disclosure in Wolff. Instead, the cited portion of Wolff's disclosure states that the radiopaque material is only on the hinges.

For the foregoing reasons, Wolff fails to anticipate claim 43. Claims 44 and 47 are dependent upon claim 43. Accordingly, the Final Rejection of claims 43, 44, and 47 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,104,404 issued to Wolff must be reversed.

8. Claim 55

Claim 55 depends from claims 54 and 20. Claim 54 recites a stent having a plurality of hoops. Claim 20 recites that the stent has at least one stent segment in combination with one or more additional stent segments. Claim 55 recites additional features about the at least one additional stent segment. For example, referring to the additional stent segment, claim 55 recites that the securing means secures apices of "juxtaposed" hoops of the additional stent segment. Applicants hereby incorporate their discussion of "juxtaposed" from their discussion of claim 54. That discussion demonstrates that Wolff does not disclose juxtaposed apices of neighboring hoops.

Accordingly, the Final Rejection of Claim 55 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,104,404 issued to Wolff must be reversed.

D. Rejection under 35 U.S.C. § 103(a) over U.S. Patent

No. 5,104,404 issued to Wolff and further in view of U.S. Patent No. 5,824,039 issued to Piplani et al.

1. Claims 45, 46, 48, and 49

Claims 45, 46, 48 and 49 depend at least from claim 54 and recite details of the radiopaque marker. For example, claim 45 recites: "wherein said element is a platinum wire." Applicants incorporate by reference the arguments made above regarding claim 54 and the features of that claim not disclosed by Wolff.

The Final Office Action does not contend that Piplani discloses all of the features recited in claim 54. Instead, paragraph 8 on page 5 of the Final Office Instead, paragraph 8 of the Final Office Action only generally states that

> Piplani teaches a stented vascular graft having gold and platinum markers as well as markers in the form of wires (see lines 22-26 of column 5 and lines 14-17 of column 7) in order to provide visibility under fluoroscopy during implantation of the device.

The cited portions of Piplani however, do not teach or suggest features recited in claims 45, 46, 48 and 49 (by means of claim 54) that are not disclosed by Wolff. Additionally, claim 43 (upon which claims 45 and 46 are dependent) recites "a radiopaque marker disposed on at least one end of the stent," and claim 44 (upon which claims 48 and 49 are dependent) recites "a radiopaque element attached to one end of said stent." (emphasis added) Instead of such a disclosure, Piplani's radiopaque markers 121 are on the main body 112 of the graft shown in Figure 4. Although Figure 4 does disclose stents in the form of spring attachment means 126 and 127 (column 5, line 31), Piplani does not disclose a radiopaque element attached to or disposed on the stents. The Examiner's other citation to Piplani, column 7, lines 14-17, discloses gold radiopaque markers on tubular member 188 within a balloon 177 shown in Figure 7. The balloon 177 is part of balloon catheter 162. It is not part of a stent. Therefore, Piplani does not disclose or suggest the invention recited in claims 45, 46, 48 and 49.

To establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." MPEP 706.02(j). Because Piplani does not disclose or suggest the features recited in

claims 45, 46, 48 and 49, those claims could not be rejected over Piplani standing alone, or in combination with Wolff.

Accordingly, because the Piplani reference fails to overcome the deficiencies of the Wolff reference, the proposed combination of Wolff with Piplani fails to establish *prima facie* obviousness. For this reason alone, the rejection must be reversed.

Further, there is no suggestion to combine Wolff with Piplani in the manner suggested in the Final Office Action and to further modify the combination in such a way as to arrive at applicants' claimed invention. The U.S. Court of Appeals for the Federal Circuit has stated that "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch,* 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing *In re Gordon,* 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)). More specifically, there is no suggestion in either reference to place a platinum radiopaque marker on the end of a stent segment in Wolff.

For the foregoing reasons, the Final Rejection of claims 45, 46, 48 and 49 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,104,404 issued to Wolff in view of U.S. Patent No. 5,824,039 issued to Piplani et al. must be reversed.

CONCLUSION

In view of the foregoing remarks, Applicants submit that the grounds for rejection of claims 20, 22-25, 31-33, 39, 41, 43-49 and 54-57 are improper. Applicants respectfully request that the Board reverse the Examiner's rejection of all pending claims.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

20. A stent as recited in claim 54 comprising at least one stent segment in combination with one or more additional stent segments.

22. A stent as recited in claim 20 wherein said one or more additional segments are axially aligned with one another.

23. A stent as recited in claim 20 wherein said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments.

24. A stent as recited in claim 20 wherein adjacent hoops are of the same diameter.

25. A stent as recited in claim 20 wherein adjacent hoops are of a different diameter.

31. An endoluminal stent as claimed in claim 54 wherein said hoops are formed of a single continuous wire.

32. An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

33. An endoluminal stent as claimed in claim 32 wherein said suture is a tied loop of thermoplastic material.

39. An endoluminal stent as claimed in claim 54 wherein each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent.

41. An endoluminal stent as claimed in claim 31 wherein said wire is nitinol.

43. An endoluminal stent as claimed in claim 54 further comprising a radiopaque marker disposed on at least one end of the stent.

44. An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque element attached to one end of said stent.

45. An endoluminal stent as claimed in claim 44 wherein said element is a platinum wire.

46. An endoluminal stent as claimed in claim 44 wherein said element is a gold wire.

47. An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque tube disposed around a part of said stent.

48. An endoluminal stent as claimed in claim 47 wherein said tube is platinum.

49. An endoluminal stent as claimed in claim 47 wherein said tube is gold.

54. A stent comprising:

a plurality of hoops aligned along a common axis, each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent; and

means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

55. A stent as recited in claim 20 wherein at least one of said additional stent segments comprises:

a plurality of hoops aligned along a common axis, each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment, and each of said hoops including a plurality of elongate

elements joined to one another and forming apices that point in a direction along the longitudinal axis of the additional stent segment; and

means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

56. A stent comprising a tubular member having a plurality of hoops aligned adjacent one another along the longitudinal axis of said tubular member, each of said hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the longitudinal axis of the stent, wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop, wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

57. A stent according to claim 56, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

IX. EVIDENCE APPENDIX

No evidence was submitted pursuant to §§ 1.130, 1.131, or 1.132 of Title 37 C.F.R. The Examiner did not enter any other evidence. The Examiner did not rely upon other evidence as to grounds of rejection to be reviewed on appeal.

X. RELATED PROCEEDINGS APPENDIX